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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,400	09/23/2003	Sylvie Bay	102.166A-1-DIV	1860

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EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/668,400	BAY ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-64* is/are pending in the application.

4a) Of the above claim(s) *45-48,53,55-57,61 and 63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43,44,49-52,54,58-60 and 62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group VI (claims 58 and 60) is acknowledged. The traversal is on the ground(s) that it is deemed that there is but a single invention present in the application and that the carbohydrate peptide conjugates of claim 43 would require the same search as well as the compositions and the method of using the carbohydrate peptide conjugates and therefore, there is but a single invention present in the application and it is believed that all should be examined together. Upon reconsideration of applicants' arguments, the restriction requirement has been reconsidered. Groups I-II(drawn to a conjugate and composition), VII and IX (drawn to a method of enhancing immune response) would be examined with the elected method group VI. Applicants' arguments with respect to Groups III-V, VIII and X are not persuasive. The claims of these groups are drawn to different compositions containing different components and different methods. These claims do not form a single invention, as different patentability determinations are required for each of the different groups. For example, a composition containing a conjugate with a tumor antigen would require a separate search

from those conjugate from bacterial or fungal origin containing carbohydrate conjugate.

The requirement is still deemed proper and is therefore made FINAL.

With respect to the election of species, Applicants elect formula (a), galactosyl of claim 44, bacterial origin of claim 49, Neisseria meningitis of claim 50 and HIV infection of claim 54 with traverse. But fails to present traversal as to why the species are not patentably distinct. Furthermore, galactosyl containing carbohydrate is a tumor antigen which has been withdrawn from consideration. Thus, the election/restriction with respect to carbohydrate will be the one that corresponds to the elected bacterial origin.

Claims 45, 46, 48, 53, 55-57, 61 and 63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

Status of Claims

Claims 43-63 are pending

Claims 45-48, 53, 55-57, 61 and 63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species.

Claims 43, 44, 49-52, 54, 58-60 and 62 are under examination.

Oath/Declaration

The oath or declaration incorrectly recites the provisional application number as 06/041,726. It should be 60/041,726. (Although the provisional application does not have to be recited in the Oath/declaration however, the error has to be corrected.)

Information Disclosure Statement

The listing of references in the specification e.g., at pages 70-86 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The abstract of the disclosure is objected to because of the inclusion a "Heading" containing the title, inventors' name and other informations. Also, because of the used of the phraseology often used in the claims, for example, "comprising".

Correction is required. See MPEP § 608.01(b). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

The disclosure is objected to because of the following informalities:

A). There is no Sequence Identifier No. for the sequences at e.g., page 17, lines 25, 27 and 28. Applicants are requested to check for other sequences in the specification that have not been assigned an ID No. as they are too numerous to mention specifically.

B). The use of the trademark TWEEN 20 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43, 44, 49-52, 54, 58-60 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claims 43 and 58 are indefinite as to the definition of "n is an integer from 1 to 9." None of Formulae(a) to (d) recites for the variable "n". "The poly-lysine carrier" lacks antecedent support from the preceding definitions of each of the variables or from any of the formulae. Is this the same as the K residue as defined?

B). The recited 103:115 in claim 47 is unclear as to the definition of colon. (It is suggested that applicants amend the claim to recite a dash(-) sign to mean residues 103 up to 115.)

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 43, 51 and 52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,676,946 ('946 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant broad claimed conjugate that recites broadly carbohydrate moiety containing a B cell epitope encompasses the specific conjugate of the '946 Patent wherein the carbohydrate moiety B and T are defined therein. (Note because the claims of the issued Patent '946 differs in scope with the presently amended claims hence, this rejection is proper, albeit applicants state the instant application is a divisional of the '946 Patent.)

Claims 43, 44, 52 and 58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29, 30, 39 and 44 of copending Application No. 09/049,847('847 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed conjugate differs from the conjugate of the '847 application in terms of the definition of the B carbohydrate moiety. The '847

recites that B as a carbohydrate moiety consisting of e.g., tumor antigen. It is considered that the tumor antigen of the '847 application contains a B cell epitope of the instant application to be considered as antigen (i.e., antigen is an epitope containing moiety). [Applicants appear to be simply multiplying the claims i.e., claiming nearly the same invention. The specification of each of the priority dates and instant invention describes only the carbohydrate moiety, as the tumor antigen, Tn.]

> This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 43, 44, 49-52, 58-60 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chong (5,679,352) in view of Birnsteil (US 20020044937).

Chong discloses at e.g., Figure 1; col. 5, line 29 up to col. 17, line 2; a peptide conjugate comprising of a carrier

comprising a dendrimeric poly-lysine to which a synthetic T cell epitope peptide (e.g., Hemophilus influenzae) is linked there to and a synthetic carbohydrate moiety of defined chemical structure (e.g., polyribosyl ribitol phosphate or its repeating units) linked to said peptide. Chong does not disclose that the T is a CD4T+ cell epitope. However, Birnsteil at paragraph [0032] discloses that the receptor used by the HIV virus during infection, namely CD4, can be used to transport nucleic acid into the cell by complexing the nucleic acid which is to be imported with a protein-polycation conjugate the protein content of which is a protein capable of binding to CD4, and bringing CD4 expressing cells into contact with the resulting protein-polycation/DNA complexes. Birnsteil discloses at paragraph [0020] that in addition to its important role in immune recognition, CD4, a glycoprotein which is present not only on T-cells but also, to a lesser extent, on monocytes/macrophages, plays a crucial role in infection with the HIV virus by acting as a receptor for the virus. HIV is the pathogen of AIDS (acquired immunodeficiency syndrome), a serious disease which is accompanied by progressive and irreversible damage to the immune system. This is caused in particular by a selective reduction in CD4+-T-cells. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use in the

conjugate of Chong another glycoprotein i.e., CD4 T+cell epitope to deliver said conjugate to deficient CD4+T disease cell caused by e.g., HIV. Said delivery of the conjugate will treat the disease caused by HIV by inhibiting said HIV effect or reduction of CD4+ cell as taught by Birnsteil. One would be motivated to substitute this CD4+T cell in a glycoprotein conjugate if treatment to one of the most serious or fatal disease of modern time, as AIDS, caused by HIV is desired.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
January 24, 2005